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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,845	11/13/2001	Allan T. Koshiol	279.196US2	8510

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT PAPER NUMBER

3762

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,845

Applicant(s)

KOSHIOL ET AL.

Examiner

George R Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-33 and 35-43 is/are pending in the application.
- 4a) Of the above claim(s) 33 and 35-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-32, 42 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/21/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 33-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-32, 42, and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The subject matter which was not described in the specification is the means or step for detecting an accidental change in the first state of the at least one programmable parameter to a second state, in combination with the other elements in the claims. It is unclear how the system operates and functions to detect an accidental change, what elements are used, how it detects an accidental change from an approved change, and if there is any difference between detecting an accidental change versus an approved change. The only reference to detecting an accidental change is given on page 8, line 6 of the specification, which does not provide any amount of direction by the inventor to determine how an accidental change is decided. The state of the prior art, the level of one of ordinary skill, and/or the level of predictability in the art do not provide any

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knowledge or teaching on how to detect an accidental change in a first state of a programmable parameter to a second state. In addition, the determination of accidental changes of other programmable parameters of claims 23, 26-30, and 32 are not described in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22, 24, 26, 42, and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Er et al (5974341). Er detects any change made to the automatic switching mode and will inherently detect an accidental change.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23 and 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Er et al. Er discloses the claimed invention except for the detection of accidental change of different parameters, such as deactivation of an executable program, expiration of battery energy, execution of a reset program, etc (claims 23, 26-30, and 32) and recording execution of an integrity correction program (claim 31). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacing and programmer system as taught by Er, with the detection of any change (including an accidental change) of different parameters, such as deactivation of an executable program, expiration of battery energy, execution of a reset program, etc., and recording execution of an integrity correction program since it was known in the art that pacer and programmer systems detect any change of different parameters, such as deactivation of an executable program, expiration of battery energy, execution of a reset program, etc, and record execution of an integrity correction program in order to provide the physician with a history of operation of the pacer to determine if the pacer is operating correctly and/or if the pacer needs to be reprogrammed.

Response to Arguments

Applicant's arguments filed 6/21/04 have been fully considered but they are not persuasive. The argument that the "specification describes a test whether the parameter values and/or states are within acceptable ranges" and therefore one skilled in the art would understand upon reading the specification that an accident change would be a change that produced an error

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is not persuasive. The specification does not state this test is a detection of an accidental change, but only that it determines whether the parameter value is not within an acceptable range. The detection of a value not within an acceptable range could mean that the value was programmed into the pacemaker in an unacceptable range or that the pacemaker calculated a value in an unacceptable range, such as calculating a pacing rate above a maximum pacing limit, and therefore the value needs changed, not that there was an accidental change of a value. Nothing in the specification relates the detection of an accidental change to the test for a value not being in an acceptable range. The only mention of logging an accidental change is on page 8, line 6, of the specification. The reference to the test is several pages away (page 10), contains alternate embodiments between the listing of the accidental change and test, and does not refer to the test as a detection of an accidental change but only as an error. In addition, the 112 first paragraph given in the action of 2/17/04 states that the accidental detection of other programmable parameters in the dependent claims, claims 23, 26-30, and 32, were not enabled. The specification does not contain any description of how the dependent claims programmable parameters are detected, such as claims 27 and 30 that state an accidental change includes detecting expiration of battery energy or use of a magnetic signal to control operation. It is unclear how you detect an accidental change of a magnetic signal that was not accidentally used but purposely used to control operation or how the expiration of battery energy is an accidental change.

If the test on page 10 is a detection of accidental change, the claims are still not enabled since several questions arise as to how these tests are performed. How does the test operate to determine if one or more parameters are within an acceptable range? What are the values

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compared to to determine if they are in an acceptable range? How does the test function to determine a programmed or calculated value from an accidental value?

The argument that Er does not detect an accidental change is not persuasive. Er detects and logs any change made for an automode switching event (columns 10 and 13) and therefore will detect any and all changes, including accidental changes, to the mode. Therefore, Er will inherently detect an accidental change. In addition, the applicant has requested prior art to show the accidental detection of the other events in claims 23 and 26-32. The examiner has provided those documents with this action. Although none of the documents specifically state that there is a "detection of an accidental change", they detect and log when a change is made and therefore will inherently detect an accidental change.

Claim 25 is not indicated as allowable since the 112 first paragraph rejection has not been withdrawn.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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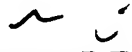
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612.

The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

5/18/4

GRE
August 18, 2004